National Black Nurses Association, Inc.

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President
Houston, TX

Millicent Gorham
Executive Director

November 17, 2005

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Commissioner of Food and Drugs
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: Docket Number 2005P-0411

Dear Mr. Commissioner:

The National Black Nurses Association (NBNA) is a nonprofit organization representing approximately 150,000 African American nurses from the USA, Eastern Caribbean, and Africa, with 83 chartered chapters nationwide. Today we are writing to express our deep concern about the improper manufacturing and marketing of bio-identical hormone replacement therapy (BHRT) products as outlined in the Citizen Petition submitted on October 6, 2005. NBNA is deeply troubled by the unethical efforts of BHRT compounding pharmacies to capitalize on women's fears and intentionally mislead women about the testing, safety, and efficacy of these products.

In the aftermath of the Women's Health Initiative (WHI), women were confused about hormone therapy (HT), and many women abandoned HT altogether. Since the WHI results were released, however, many women have returned to hormone therapy to control their menopausal symptoms. NBNA believes that based on the best decisions made by the health care provider and their patient, hormone therapy may be prescribed at the lowest possible dose for the shortest duration of time.

The negative publicity surrounding the WHI has generated a new market for certain bio-identical products, which are touted as miracle drugs which "reliev[e] many symptoms of menopause without the risk of side effects" (See Brochure for Health Max Pharmacy Regional Symposium on Bio-Identical Hormone Replacement Therapy (N.Y., April 30, 2005)).

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In an opinion as expressed by the American College of Obstetricians and Gynecologists, the major concern is that most compounded products have not undergone rigorous clinical testing for safety or efficacy. Issues of quality assurance regarding the purity, potency and quality of compounded products are a concern. While NBNA supports the legitimate compounding of medicines for distinct patient needs, NBNA believes that the practices of many pharmacies compounding BHRT products rise above and beyond legitimate compounding activities. Instead of compounding products for particular patients, many of these compounding pharmacies promote these untested and unregulated products to all women as complete substitutes for FDA-approved HT, without any evidence of safety or effectiveness.

While compounding pharmacies certainly have the right to advertise their services to healthcare professionals and patients, labeling and advertising of any and all pharmaceuticals must be truthful. Any representation that BHRT is somehow safer and/or more effective than FDA-approved HT products is misleading at best, and completely false at worst. Furthermore, any safety and effectiveness information must be fairly balanced with information about side effects and contraindications, and the product labeling must include the appropriate Black Box warning. It is FDA's job to ensure that proper substantiation exists for all safety and effectiveness labeling claims.

For these reasons, the National Black Nurses Association urges FDA to investigate the questionable practices of compounding pharmacies promoting BHRT products, and to take appropriate enforcement action where warranted.

Thank you for your consideration of this important public health issue.

Sincerely,

Millicent Gorham

Millicent Gorham
Executive Director